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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,361	05/31/2005	Gwenn E. Kennedy	2G.02.1-084 US	7398

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GARDNER GROFF GREENWALD & VILLANUEVA, PC
2018 POWERS FERRY ROAD
SUITE 800
ATLANTA, GA 30339

EXAMINER

NGUYEN, HUONG Q

ART UNIT	PAPER NUMBER
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3736

NOTIFICATION DATE	DELIVERY MODE
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10/08/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/505,361

Applicant(s)

KENNEDY ET AL.

Examiner

HELEN NGUYEN

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 August 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/22/2006 and 6/7/2006</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

1. The preliminary amendment dated 8/19/2004 is acknowledged. The amendments to the specification and the claims are acknowledged. **Claims 1-50** remain pending and under prosecution.

Priority

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged, namely, priority as 371 of PCT/EP03/01700, filed on 2/20/2003.

3. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in Application No. 10/505361, filed on 8/19/2004. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

4. Applicant also appears to claim priority to provisional application 60/411834, filed 9/17/2002. However, this has not yet been verified.

Information Disclosure Statement

5. The information disclosure statement (IDS) submitted on 5/22/2006 and 6/7/2006 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. **Claims 1, 49, and 50** are rejected under 35 U.S.C. 102(e) as being anticipated by

Moerman et al (US Pat No. 6706159).

8. Moerman et al disclose a cartridge for use with a blood analyzer device having a body 81, the cartridge comprising:

a carrier 85 that is movable with respect to the device body;

a plurality of pricking elements 844 arranged on the carrier, each of the pricking elements for puncturing skin to produce a sample of blood;

a plurality of testing elements 812 arranged on the carrier, each of the testing elements for accommodating one of the samples of blood;

wherein the cartridge is receivable within the device body with the carrier movable with respect to the device body through cam ring 86 and stepper motor 803 so that the pricking elements and the testing elements can be brought one after another into a working position for obtaining the blood sample and testing the blood sample, best seen in Figure 8A-F.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. **Claims 1-14, 16, 18-21, and 23-50** rejected under 35 U.S.C. 103(a) as being unpatentable over Schraga (US Pat No. 6228100) in view of Moerman et al.

11. In regard to **Claims 1, 49, and 50**, Schraga discloses a blood analyzer comprising a device body 45, 46 with a blood sampling device which has a pricking element 70, forming a complete system that can be handled as a single device, whereby the device body has a pricking position which is assigned to the working position of the pricking element for coming in contact with a skin surface of a user and a charging position designed at another location on the body of the device for charging a minimal quantity of blood coming from the previously pricked skin surface, whereby a plurality pricking elements 70, 70' can be inserted into the device and can be brought one after the other into a working position for performing multiple measurements, whereby when a pricking element is positioned in its working position, the pricking element can be inserted into the skin surface of a user which is brought into the pricking position, the pricking elements are arranged on a carrier 40 which is rotatable with respect to the body of the device and can be inserted together with it into the device, and by rotating the carrier the pricking elements can be brought into different working positions with respect to the body of the device, best seen in Figures 1 and 4.

12. However, Schraga does not disclose the blood analyzer comprises a plurality of testing means. Moerman et al teach an analogous blood analyzer comprising a plurality of testing means 812 used in conjunction with a plurality of pricking means 844 to effectively provide an integrated lancing and testing device, best seen in Figure 8A-F. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the blood analyzer of Schraga include a plurality of testing means as taught by Moerman et al such that the testing means is for accommodating a minimal quantity of blood, the analyzer device comprises an electronic analyzer and having a display device (Figure 8B), such that blood coming from the skin surface can be charged to a testing means by being brought in contact with the skin surface in the charging positions to effectively provide an integrated lancing and testing device.

13. Claim 2: Moerman et al disclose the pricking elements 844 and the testing means 812 are arranged on the same carrier 85, which can be handled manually.

14. Claim 3: Moerman et al disclose the carrier comprises a first carrier part 84 for the testing means 812 and a second carrier part 87 for the pricking elements 844, best seen in Figure 8A-F.

15. Claim 4: Moerman et al disclose the two carrier parts can be assembled to form a manually operable unit.

16. Claim 5: Moerman et al disclose the carrier parts can be linked together in a rotationally fixed manner.

17. Claims 6-8: Schraga discloses the carrier 40 has a central recess within which a drive device 48 for the blood sampling device is provided.

18. Claims 9-10: Schraga in combination with Moerman et al disclose the pricking elements are arranged on the carrier in such a way that when they are in the working position, they execute a pricking movement in the radial direction with respect to the rotatability of the carrier, best seen in Figure 4 of Schraga and Figure 8 of Moerman et al.
19. Claim 11: Schraga discloses the pricking elements 70 are surrounded by a sterility barrier 72 on the carrier before execution of a pricking operation, best seen in Figure 4.
20. Claims 12-14, 16: Schraga in combination with Moerman et al disclose before execution of a pricking operation, a particular pricking element is arranged in a sleeve means 52 (Schraga), forming a cylindrical space, and is held by a plunger means 24 which is movable in the sleeve means, best seen in Figure 2.
21. Claims 18-21: Schraga in combination with Moerman et al disclose multiple recesses in the carrier in each of which is arranged a pricking element.
22. Claim 23: Schraga discloses the pricking elements 70 carry a safety cap means 72 on their free end before executing a pricking operation, best seen in Figure 4.
23. Claims 24-25: Schraga discloses the safety cap means 72 is releasable from the pricking element immediately before execution of the pricking operation and brought into a receptacle space, best seen in Figure 4 and 6.
24. Claim 26: Moerman et al disclose the test means 812 are arranged on the carrier in such a way that they are axially oriented with respect to the rotatability of the carrier, best seen in Figure 8.

25. Claims 27-28: Schraga in combination with Moerman et al disclose the carrier 40 has a carrier part for the test means, the carrier part in particular being in the form of a ring disk, the plane of the carrier part being oriented perpendicular to the axis of rotation of the carrier.
26. Claims 29-30: Schraga discloses the charging position can be covered by a movable cover part when it is not needed, best seen in Figure 1.
27. Claim 31: Schraga discloses the drive device for the pricking element can be activated by clamping a spring means, best seen in Figure 2.
28. Claims 32-37: Schraga discloses a manually movable control element 24 is provided and is connected to the drive device for the pricking element and to the rotatable carrier 40, so that when there is a movement of the control element, the drive device for the pricking element is activated and there is a rotational movement of the carrier.
29. Claims 38-40: Schraga discloses a triggering device 35 for actuating the drive device for the pricking element can be operated by contact of the skin surface with the pricking position, best seen in Figure 2.
30. Claims 41-43: Schraga discloses a retraction mechanism 27 is provided by means of which a particular pricking element 70 can be retracted directly following the pricking operation, best seen in Figure 2.
31. Claim 44: Schraga in combination with Moerman et al disclose a safety device which allows deployment of the pricking operation only when the device is being handled properly.
32. Claim 45: Moerman et al disclose the number of test means 812 that can be handled as one unit amounts to 5 to 15, best seen in Figure 8.

33. Claim 46: Schraga in combination with Moerman et al disclose the device has an outside contour that is essentially in the form of a circular disk.

34. Claim 47: Moerman et al disclose a time display device, best seen in Figure 8A-B.

35. Claim 48: Moerman et al disclose the housing body can be worn on the wrist of a user by means of a strip 82 that can be attached to it, best seen in Figure 8A-B.

36. **Claims 15, 17, and 22** rejected under 35 U.S.C. 103(a) as being unpatentable over Schraga in view of Moerman et al, further in view of Charlton et al (US Pat No. 5738244).

37. Schraga in combination with Moerman et al disclose the invention above as claimed but do not disclose a film covering the sleeve means in the form on a circular shape, or used as a sterility barrier. Charlton et al teach an analogous multiple testing means comprising a circular film 64 covering the testing means for an effective sterility means, best seen in Figure 5.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have the invention of Schraga and Moerman et al include a circular film to cover the sleeves as taught by Charlton et al to provide an effective sterility barrier.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HELEN NGUYEN whose telephone number is (571)272-8340. The examiner can normally be reached on Monday - Friday, 9 am - 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. N./
Examiner, Art Unit 3736

/M. H./
Supervisory Patent Examiner, Art Unit 3736